



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 09/972,916 Confirmation No.: 4645
Applicant : Peter M. THULÉ, M.D.
Filed : October 10, 2001
Title : GLUCOSE SENSITIVE REGULATOR OF INSULIN
TRANSCRIPTION
Group Art Unit : 1635
Examiner : ANGELL, Jon E.
Atty. Docket No. : US 1292/01(VA)

DECLARATION OF PETER M. THULÉ UNDER 37 CFR § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Peter M. Thulé, M.D., hereby declare and state as follows:

1. I am the sole inventor of the invention(s) disclosed in Provisional Application S.N. 60/239,113, filed October 11, 2000.

2. I am the sole inventor of the above-captioned application S.N. 09/972,916 (hereinafter "the '916 application") filed October 10, 2001, which claims priority based on the provisional application identified above in paragraph

1.

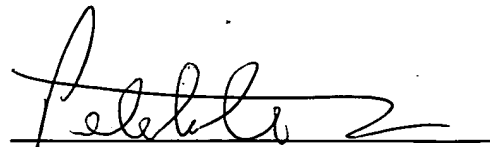
3. I have reviewed and am familiar with the Office Action of July 28, 2004, issued by the U.S. Patent and Trademark Office in the '916 application.

4. I am a co-author of the publication Glucose regulated production of human insulin in rat hepatocytes, Gene Therapy (2000), 7(3):205-214, which was published on February 15, 2000 (hereinafter "the Gene Therapy publication").

5. I am the sole inventor of the subject matter relied on by the Examiner in the Gene Therapy publication to reject Claims 1-16 under 35 U.S.C. §102(a).

6. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

1/21/05
Date


Peter M. Thulé, M.D.